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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,717	03/12/2001	Terry B. Storm	01948-051003	2953

7590

10/03/2002

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 10/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/804,717	STORM ET AL.	
	Examiner	Art Unit	
	Anne M Wehbé	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. 120, 121, or 365(c). **Copendency** between the current application and the prior application is required.

The application data sheet for this application states that this application is a continuation of U.S. application no. 08/273,402, filed on 7/11/94, now issued patent no. 5,958,403, which is a continuation in part of U.S. application no. 08/024,569, filed on 3/1/93, abandoned 7/12/94, which is a continuation in part of U.S. application no. 07/843,731, filed on 2/28/92, abandoned 8/6/93. 35 U.S.C. 120 states that in order for an application to receive the benefit of the filing date of an previously filed application, the application must be filed **before** the patenting or abandonment of the first application. U.S. application no. 08/273,402 issued as patent no. 5,958,403 on Sept. 28, 1999. The instant application was not filed until March 12, 2001, more than a year after the issue date of the 5,958,403 patent. Thus, this application is denied benefit of the filing date of parent applications. The effective filing date of the instant application is therefore the actual filing date of the application, March 12, 2001.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51-55 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,958,403 (9/23/99), hereafter referred to as the '403 patent. Please note that this application is denied the benefit of priority to the application which resulted in the '403 patent based on the fact that the instant application was filed more than a year after the issuance of the '403 patent, see the discussion under the section entitled *Priority* above. Thus, the '403 patent qualifies as prior under 35 U.S.C. 102(b).

The specification of the '403 patent and the instant application are identical. Columns 3-4 in particular teach methods for inhibiting rejection of a transplanted tissue in a mammal, involving introducing into a cell, either in vivo or ex vivo, DNA encoding an immunosuppressive protein such that the cell expresses the immunosuppressive protein ('403, column 3, lines 59-62). The specification further teaches that when the DNA is introduced into cells ex vivo, the method further includes the transplantation of those cells into the mammal ('403, column 3, lines 63-65). In column 4, the specification teaches that the cells can be allogeneic or xenogeneic and that the immunosuppressive protein can be IL-10 or TGF- β ('403, column 4, lines 12-15, and 41-46).

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Examples of DNA constructs encoding either IL-10 or TGF- β useful for the instant methods are disclosed in column 18, lines 27-62). Thus, by teaching all the limitations of the claims as written, the '403 patent anticipates the instant invention.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703)-306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

